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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,566	09/10/2003	Christophe Dupont	2756.001	4677

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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,566	DUPONT ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12 and 14-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12 and 14-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks filed 20 August 2007 have been acknowledged and duly made of record.

In light of the arguments made by applicants, reconsideration by the Examiner is extended.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant invention.

Status of the Claims

Claims 1-4, 6-12, and 14-17 are pending in the application. Claim 13 is withdrawn from future consideration. Claims 1-4, 6-12, and 14-17 are pending for further prosecution on the merits.

Objection

The disclosure is objected to because of the following informalities: the disclosure lacks a brief description of the Drawing.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-12, and 14-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer (USPN 4,836,217), Counter (USPN 3,837,340) , Quisno (USPN 4,788,971) and Carvalho et al. (USPGPUB 2003/0064088 A1) in view of Schoendorfer (USPN 5,438,984), Axen et al. (USPN 3,645,852) and Polypropylene, [online] retrieved 01/05/2008 92008), retrieved from http:pslc.ws/mactest/pp.htm, printed pages 1-3.

Fischer teaches a novel device and method for carrying out occlusive epicutaneous tests (patch tests). This type of test is employed for detecting contact allergy to some specific substance (allergen) or for testing allergenic and/or irritant properties of a substance. The invention is characterized in that the test substance is incorporated in a **dry film** (abstract only).

According to the instant specification, the expression, "electrostatic support" denotes any support made of a material capable of accumulating electrostatic charges and of conserving them by thus, developing maintaining forces, **in particular by rubbing, heating or ionization, or any other technique** (fourth paragraph, pg. 9).

Fischer, in kind, teaches that there are two important steps in the manufacturing procedure which are of prime importance for the result obtained: (1)

The test allergen has to be distributed uniformly in the film-forming material. (2) The film carrier has to be coated reproducibly with a film of even thickness. If a hydrophilic vehicle is chosen to be employed on a film carrier which is too hydrophobic in character it may turn out to be difficult to uniformly coat the carrier with the vehicle. In such a case the carrier may be

treated so as to be made more hydrophilic. Thus, for instance, a polyester film may be treated for a short period of time in an electric field (e.g. corona discharge treatment), or a polyethylene film may be partially oxidized to introduce polar structures (column 5, lines 43-56). The above explanation would be recognized by the skilled artisan as an example of electrostatic support according to the definition disclosed in the instant specification.

However, Schoendorfer does teach invention is an improved method and apparatus for collecting analytes on a dermal patch, **where the patch controls the ionization state of the analyte. This can be accomplished by delivering electricity to the patch or by a buffer or other means for controlling the pH of fluids entering the patch**. Analytes in perspiration can be concentrated on the patch without the occurrence of significant back-diffusion of the analytes (abstract only).

The instant invention teaches electrostatic forces [which] denote any support made of a material capable of accumulating electrostatic charges and of conserving them by thus, developing maintaining forces, **in particular by rubbing, heating or ionization, or any other technique.** This instant disclosure is, thus, made obvious in view of Schoendorfer. Schoendorfer, in a word, does adequately address factors associated with electrostatic support via a physicochemical process between the support and the skin and via external stimulation (an electrical charge).

Fischer does not teach a plurality of allergens (which are separated) but embedded in the hollow of a dermal patch. However, Counter teaches live avirulent virus used to immunize against smallpox, measles, or mumps, or a combination of them, **is applied as a dry deposit on a physiologically inert surface of a device adapted to be held against the unbroken skin** of

an animal to be immunized. Illustratively, cowpox virus as a dry surface deposit is applied at the midpoint of a plastic bandage; it is used by applying the bandage for a period of time to a body site at which the immunization is to be applied (abstract only).

More specifically, Counter teaches the inventive concept of the application of poly-therapy/poly-pharmacy within the confines of a dermal patch. Counter does not teach the central issue of the inventive objective which is drawn to an allergenic response but does teach the limitation of a patch/support which is embedded with several key virus strains in order to determine immunization. The skilled artisan would instantly recognize the interchangeability of any bioactive agent in exchange for another bioactive agent, in view of the dermal patches. In other words, the virus agents as disclosed in Counter could conceptually be interchanged with any other bioactive agents drawn to an array of other disease state determinations and/or treatments.

Quisno teaches a patch system for use on the skin of a human or animal subject **for predictive testing, diagnostic testing and to serve as a dermal delivery system for drugs**. The patch system comprises an open, one-piece, inverted dish-shaped housing of non-toxic, inert, soft and flexible material. About its periphery the housing terminates in at least one and preferably a pair of parallel, spaced, continuous, skin-contacting edges. The housing may contain an absorbent pad. About its periphery and spaced slightly upwardly from the one or more skin-contacting edges, the housing has a planar flange extending outwardly from its exterior surface. The bottom surface of the flange is adhesive coated. The adhesive coated flange affixes the housing to the skin. Prior to use, the housing and its peripheral flange may be provided with a protective release paper (abstract only).

Quisno does not specifically teach *the hermetically closed space between the support and skin.*

However, Carvalho et al. does teach a drug reservoir [which] is isolated from adjacent structures and fluids by an outer layer of polymer **impermeable** to the carried therapeutic agent. A delivery port or interface window is provided in the housing of the device for providing targeted release of a drug contained therein. The interface window is sealed to the tissue surface **by a surrounding sealing base associated to designed structures to assure the hermetical seal necessary for the control of the interface diffusion mechanism.** The delivery port or interface window may be covered by a structural layer that is permeable to the therapeutic agent contained within the device reservoir, or by a layer that is biodegradable. In certain instances, the therapeutic agent is contained in a slow release formulation that does not require that the delivery port or interface window be covered during implantation, so that a portion of the agent bolus in the device reservoir is directly contacted with the target tissue. **In an embodiment, the device housing includes an attachment mechanism for attaching the device to a target tissue. This is provided by a series of structures that in combination allow a hermetical seal between the system and the targeted tissue** (paragraph 69).

Quisno does not teach polypropylene as a support but Axen et al. does disclose relevant embodiments drawn to natural properties, characteristics, and susceptibilities of cellulose polymers. Specifically, in addition to polypropylene (the elected support material), polyvinyl chlorides, polystyrenes, polycarbonates and polyacrylics are described in detail in relation their myriad of mutable properties required for the binding of water-soluble proteins and peptides.

For evidentiary purposes, polypropylene has been described as one of those rather versatile polymers out there. It serves double duty, both as plastic and as a fiber. As a plastic it's used to make things like dishwasher-safe food containers. It can do this because it doesn't melt below 160°C, or 320°F. Polypropylene, a more common plastic, will anneal at around 100°C, which means that polyethylene dishes will warp in the dishwasher. As a fiber polypropylene is used to make indoor-outdoor carpeting, the kind that you always find around swimming pools and miniature golf courses. It works well for outdoor carpet because it is easy to make colored polypropylene, and because polypropylene doesn't absorb water, like nylon does

Structurally, it's a vinyl polymer and is similar to polyethylene only that on every other carbon atom in the backbone chain has a methyl group attached to it. Polypropylene can be made from the monomer propylene by Ziegler-Natta polymerization and by metallocene catalysis polymerization (page 1).

Thus, it would have been prima facie obvious at the time of invention for the skilled artisan to at once recognize with a reasonable expectation of success via the incorporating together or combining and/or, modification of the methods and teachings of Fischer (USPN 4,836,217), Counter (USPN 3,837,340), and Quisno (USPN 4,788,971), Schoendorfer (USPN 5,438,984), Axen et al. (USPN 3,645,852) and Polypropylene. Fischer teaches the inventive objective of claimed invention. Motivation to combine to Fischer is exemplified via the teachings of Counter which teaches a dry deposit as does Fischer by which bioactive agents are the general consistency, either in monotherapy or polytherapy. Schoendorfer provides adequate motivation by teaching the limitation of electrostatic support. Quisno further provides motivation to combine the references *supra* via the disclosure a patch system for use on the skin of a human or

animal subject **for predictive testing, diagnostic testing and to serve as a dermal delivery system for drugs**. Carvalho et al., however, teaches embodiments of drug- impregnated patches and transdermal supports drawn specifically to the concerns for achieving optimal hermetically sealed transdermal devices. The motivation of Carvalho et al. in the reference is based on the prevention of extravasation of the bioactive drug onto healthy tissue, thereby compromising the hermetic seal or adhesive properties of the transdermal system. Carvalho et al. teach the inventive objective which addresses the essential property of any transdermal patch; the essential property being that the transdermal system should have uncompromised adhesive attachment to the tissue or organ area peripheral to the target tissue area. Thus, in view of the deficiency in Quisno to teach ' *a hermetic seal*', Carvalho et al. adequately addresses the claimed inventive objective (which is already well-known in the art). The Polypropylene reference discloses information on the natural properties of cellulose plastics/ polymers which are indicated for use as supports (dermal patch component) due to well-established art on the usefulness of polypropylenes as support devices, i.e., dermal patch component drawn to lending a supportive dressing type property to the area of skin being tested or treated. The consistency of the cellulosic type plastics also aid in the physicochemical processes drawn to electrostatic activity and reaction of the bioactive material embedded in the hollow of dermal support/patch as has been explained above. The skilled artisan would instantly recognize that the inventive objective of Counter could just as readily be interchanged, drawn to the inventive objective of the claimed invention. Instant claim 17 is made obvious due to the combining of the teachings of Fischer and the methods (with the exception of the bioactive material) of Counter. Thus, the claimed invention is made obvious over the teaching, methods, and modifications and would be readily

apparent to the skilled artisan that the actual claimed invention could be reasonably encompassed by the references *supra.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Wang

SHENGJUN WANG
PRIMARY EXAMINER

TEB